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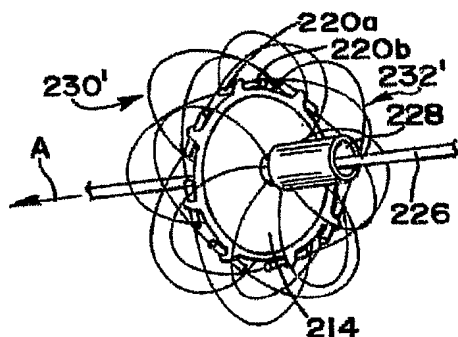
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(54) Title: AN IMPLANT FOR OCCLUDING A PASSAGE



(57) Abstract: An implant for occluding a passage in a circulatory sys-
tem is provided comprising wire-like members being attached to first and
second holders, wherein the distance between said holders being reduce-
able in a manner to cause the members to execute a twisting motion to
yield a plurality of generally radially extending loops forming at least one
fixation structure, thereby expanding, preferably unfolding, the occlud-
ing body. This implant is at least partly made of biodegradable material.

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AN IMPLANT FOR OCCLUDING A PASSAGE

5

FIELD OF THE INVENTION

The present invention generally relates to an implant device for closing a body passage (e.g., an aperture through the atrial diaphragm or septum or the ventricle diaphragm or septum of a heart) or in a body channel, and more particularly comprising an occluding
10 or closing body which is expanded and fixed into place at the passage area to be occluded/closed.

BACKGROUND OF THE INVENTION

15

By way of example EP-A-0 362 113 shows a device for closing a passage in the heart of patients, wherein the closing part runs the risk of tipping over and thereby causing the passage to be exposed in passing through the heart. The cause of the non-secure closing capacity is the relative unfixed maneuverability for the closing part when applied
20 around the passage, and that the application takes part long before it has arrived in its final position around the passage in the heart.

WO 02/38051 discloses implants for occluding a passage in a circulatory system. This implant has its particular application as a cardiological implant by means of which it is
25 possible, for example, to close an aperture through the auricle diaphragm or the ventricle diaphragm of a heart. It is arranged to be deployed or built up (i.e., assembled) at a desired location in the body (e.g., the heart), in contrast to known other implants (e.g., so-called umbrellas and sails) that are instead extended as soon as the compressed umbrella leaves its insertion sheath. It includes a plurality of thin wire-like members each
30 having a proximal and a distal end. The members are made of non-bendable material. Two holders are provided to which these ends are attached. When the distance between the two holders is reduced the non-bendable members are caused to execute a twisting motion yielding in a plurality of radially extending loops, which are fixed in their posi-

BESTÄTIGUNGSKOPIE

tion. In one embodiment, a balloon structure is expanded. In another embodiment, an occluding body arranged in the middle between the two holders is expanded by the twisting members. WO 02/38051 suggests to use nitinol as material for the wire-like members or threads.

5

It is therefore an object of the present invention to provide, based on the device disclosed in WO 02/38051, an occlusive device being more acceptable by a living body, especially by a human body.

10

SUMMARY OF THE INVENTION

The foregoing object is achieved by means of an implant according to the present invention, which is substantially characterized in that it is compressible for insertion through
15 a delivery mechanism and is deployable for occluding the passage in the circulatory system, wherein the implant is at least partially made of at least some biodegradable material.

This object is further achieved by means of a device according to the present invention,
20 which is substantially characterized in that it comprises

- a plurality of thin, preferably stiff, members each having a proximal and a distal end;
- a first holder to which the distal ends of said members are attached;
- a second holder to which the proximal ends of said members are attached;
- 25 an expansible, preferably foldable, occluding body attached to said members;
- said plurality of members with said occluding body forming an elongated article extending along a longitudinal axis and being adapted for insertion through a delivery mechanism in an insertion condition;
- said members being attached to said first and second holders and the distance between said holders being reduceable in a manner to cause said members to execute
30 a twisting motion relative to said axis to yield a plurality of generally radially extending loops forming at least one fixation structure, thereby expanding, preferably unfolding, the occluding body and

said at least one fixation structure being fixable in a final occluding condition, wherein one or more of said plurality of members, said first holder, said second holder and said expansible occluding body is made of at least some biodegradable material.

5

The implant according to the invention is formed partly or entirely of biodegradable or bioabsorbable material(s). A living body can degrade or absorb it, therefore minimizing the risk of non-compliance with the immunological system of the living body.

10 Usually, an intravenous delivery mechanism is used. However other delivery mechanisms, such as one using the esophagus can be used.

In a preferred embodiment, at least the wire-like members or threads and/or the occluding body are made of biodegradable or bioabsorbable material.

15

These and other advantages and objects achieved by the present invention will be further appreciated and understood upon consideration of the following detailed description of certain embodiments taken in conjunction with the drawings in which:

20

BRIEF DESCRIPTION OF THE DRAWINGS

- FIG. 1 shows an initial position for an implant according a first embodiment of the invention, the implant being seen from the side and from one end respectively;
- 25 FIG. 2 shows the implant of FIG. 1 at a between position during extension seen from the side and one end respectively;
- FIG. 3 shows the implant of FIG. 1 completely extended seen from the side and one end respectively;
- 30 FIG. 2A shows the implant of FIG. 1 in a perspective view during extension;
- FIG. 3A shows an end view of the implant of FIG. 1 in its extended position;
- FIG. 4 shows schematically the principle for building up the hub and connection of the implant of FIG. 1 to it and the final position of the implant in completely

- extended condition seen from the side;
- FIG. 5 shows a second embodiment of the present invention in a perspective view in an initial position;
- FIG. 6 shows the implant of FIG. 5 in a perspective view in a first partially
5 deployed position;
- FIG. 7 shows the implant of FIG. 5 in a perspective view in a second partially deployed position;
- FIG. 8 shows the implant of FIG. 5 in a perspective view in a fully deployed condition;
- 10 FIG. 9 shows the implant of FIG. 5 in a side view in a fully deployed condition; and
- FIG. 10 shows an enlarged perspective view of a portion of the implant according to FIG. 5, without the membrane and loops, detailing the locking hubs.

15

PREFERRED EMBODIMENTS

The device according to the invention is based on the implants disclosed in WO 02/38051, the disclosure thereof is incorporated in this description by reference.

20

This device or implant is employed as an implant for closing an internal passage, for example, an aperture in the auricle diaphragm or the ventricle diaphragm of a heart, or in a desired body channel which one wishes to close. A closing body is deployed or unfolded at the location. More particularly, the closing body is arranged to be expanded,
25 preferably unfolded, at the position of the intended closing spot, after insertion through a body vein.

30

The closing body consists for example of an inflatable balloon or of an expansible, preferably unfoldable, disk-shaped member. The closing body is arranged to be dilated, expanded or unfolded radially by means of a number of stiffening means, which are made of non-bendable material and therefore twist when the distance between their fixed ends is reduced. A locking mechanism, preferably consisting of snap together members, are provided for locking the wire-like members in their twisted position.

This implant is delivered to the location for application in the form of a thin, elongated device and is then expanded or unfolded into its locking position.

5 FIGS. 1 - 4 disclose a first embodiment of a device 101 being formed as an implant for closing a passage. This implant utilizes the rotating quality of non-bendable materials when they are compressed, and when the ends move past a critical point. For this object, there are thin threads attached around an inner core of material in each end inside a balloon. The distal and the proximal balloons have a further opening between them and the
10 diameter of the balloon at its smallest part corresponding to the ASD-size, i.e. that it is somewhat but not much larger. The balloons are inflated by means of a contrast fluid whereupon the furthestmost, as seen in the direction of insertion, attachment point of the threads are slowly pulled back at the same time as the nearest, as seen in the direction of insertion, are pushed ahead, i.e. in the direction toward each other. At a critical position,
15 the threads twist or spiral sideways and maintain a circular shape, which desired shape is used according to the present invention. In position, the balloons are evacuated and the threads are locked in the twisted spring-like position.

The implant comprises a closing body 106 which is attachable at the passage, alone or
20 in combination with further sealing means in a radial direction 107 which is also an expanding stiffening fluid tight closing body. The body 106 is arranged that after insertion through a body vein (not shown) in its longitudinal direction 150, it will be built up at the position 109 for the intended closing spot.

25 A number of threads 151 which in the shown embodiment are eight in number, are arranged of such a material and with such qualities that they twist automatically sideways to form a circular or loop shape when compressed longitudinally, as is shown in FIG. 3, and are locked in the twisted, spiral or coil-like position for interconnecting the two chambers, and so on, against each other. The body 106 is formed by a plurality of thin
30 threads or wires, which are attached respectively in axial direction 150, 152 relative to each other on movable holder nuclei 153, 154. The threads 151 are arranged to twist sideways in the same direction and then to assume a somewhat circular shape 155, similar to a flower, a propeller or an umbrella, with circular shape and arranged with suit-

able means for closing the passage.

For example, the closing portion may be formed of layers of watertight material connected to the threads 151. These layers and/or the threads are preferably made of a biodegradable material as disclosed in the following example. Preferably, the layers and the threads are made of a biodegradable material. Preferably, the whole implant is made of a biodegradable material.

In the example according to FIG. 4 the threads 151 are shown attached with different inclination x, y with reference to the respective separate holder nuclei 156, 157. The threads 151 are arranged to be mutually forced to be directed toward that holder nucleus 157 from which the threads 151 depart with the largest angle y, as calculated from the centre axis 158 of the holder nuclei, with similar angle z for the different threads 151.

FIGS. 5 - 10 further illustrate a second embodiment of the present invention: FIG. 5 shows the implant 200 of the present invention in a perspective view in an initial position, i.e., before the device is applied to the passage in a circulatory system and deployed. In the figures a plurality of thin stiff generally inextensible, but somewhat flexible, members or wires 202 are provided. The whole implant, but at least the members 202 are preferably biodegradable. While the figure shows eight members, it should be understood that the number of members can be varied and not change the spirit of the invention.

In one embodiment of the invention, the members 202 may be formed of a biodegradable or bioabsorbable material consisting of a polymer that exhibits a relatively high degree of biocompatibility. These materials have been previously used in stents, for example. Bioabsorbable implantable occlusive devices of the present invention may be made completely or partly of poly(alpha-hydroxy acid) such as polylactide [poly-L-lactide (PLLA), poly-D-lactide (PDLA)], polyglycolide (PGA), polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), or related copolymers materials, each of which have a characteristic degradation rate in the body. For example, PGA and polydioxanone are relatively fast-bioabsorbing materials (weeks

to months) and PLA and polycaprolactone are relatively slow-bioabsorbing material (months to years). Reference is made to Enhancement of the Mechanical properties of polylactides by solid-state extrusion, W. Weiler and S. Gogolewski, Biomaterials 1996, Vol. 17 No. 5, pp. 529-535; and Deformation Characteristics of a Bioabsorbable In-

5 travascular Stent, Investigative Radiology, December 1992, C. Mauli, Agrawal, Ph.D., P.E., H. G. Clark Ph.D., pp. 1020-1024.

Mechanical properties of these materials generally increase with increasing molecular weight. For instance, the strength and modulus of PLA generally increase with increas-

10 ing molecular weight. Degradation time generally decreases with decreasing initial molecular weight (i.e., a mesh device made of a low molecular weight polymer would be bioabsorbed before a mesh device made of a high molecular weight polymer). Low molecular weight PLA is generally more susceptible to thermo-oxidative degradation than high molecular weight grades, so an optimum molecular weight range should be selected to balance properties, degradation time, and stability. The molecular weight and

15 mechanical properties of the material generally decrease as degradation progresses. PLA generally has a degradation time greater than 1 year. Ethylene oxide sterilization process (EtO) is a preferred method of sterilization. Furthermore, PLA has a glass transition temperature of about 60 degrees C, so care must be taken not to expose products

20 to high temperature environments for substantial time periods (temperatures greater than 60 degrees C), to avoid the possibility of dimensional distortion or other degradation effects.

PLA, PLLA, PDLA and PGA include tensile strengths of from about 40 thousands of pounds per square inch (ksi) to about 120 ksi; a tensile strength of 80 ksi is typical; and

25 a preferred tensile strength of from about 60 ksi to about 120 ksi.

Polydioxanone, polycaprolactone, and polygluconate include tensile strengths of from about 15 ksi to about 60 ksi; a tensile strength of about 35 ksi is typical; and a preferred

30 tensile strength of from about 25 ksi to about 45 ksi.

PLA, PLLA, PDLA and PGA include tensile modulus of from about 400,000 pounds per square inch (psi) to about 2,000,000 psi; a tensile modulus of 900,000 psi is typical;

and a preferred tensile modulus of from about 700,000 psi to about 1,200,000 psi.

Polydioxanone, polyeaprolactone, and polygluconate include tensile modulus of from about 200,000 psi to about 700,000 psi; a tensile modulus of 450,000 psi is typical; and
5 a preferred tensile modulus of from about 350,000 psi to about 550,000 psi.

PLLA filament has a much tower tensile strength. and tensile modulus than, for exam-
ple, Elgiloy.RTM. metal alloy wire which may be used to make braided mesh devices or
elements. The tensile strength of PLLA is about 22% of the tensile strength of El-
10 giloy.RTM. The tensile modulus of PLLA is about 3% of the tensile modulus of El-
giloy.RTM. mechanical properties and self-expansion are directly proportional to tensile
modulus of the material. As a result, a PLLA filament or braided or woven element
made to the same design as the implant of the present invention may have poor me-
chanical properties and may not be functional. The polymeric inextensible members 202
15 should have radial strength similar to meta members and should have the required me-
chanical properties capable of bracing open endoluminal or the like strictures.

Each member 202 has a proximal end 204 and a distal end 206. The proximal end 204 is
shown here positioned adjacent the user's hand 208 while the distal end 206 enters the
20 passage (not shown) first. In practice, of course, the hand would typically be much fur-
ther away, given that the device will be introduced intravenously. The distal ends 206 of
the inextensible members 202 are attached to a first holder 210 that has a ring shape like
that of a circular hub or hub flange. The proximal ends 204 of the inextensible members
202 are attached to a second holder 212 similar to the first holder 210, i.e., a ring-
25 shaped holder or hub.

At a point generally midway between the first holder 210 and the second holder 212 an
expansible, preferably unfoldable, occluding body 214 is attached to the members 202.
The occluding body 214 may be a generally circular, disc-shaped member, and may be
30 made of a flexible fabric-like material consistent with surgical use and more preferably
of a biodegradable material. The occluding body 214 has a distal face 216 oriented to-
ward the distal ends 206 of the members 202 and a proximal face 218 oriented toward
the proximal ends 204 of the members 202. The members 202 preferably have a thick-

ened portion 220 where they pass through openings 222 in the occluding body 214. The thickened portion 220 is actually two parts 220a, 220b which serve to capture and mount the occluding body 214 therebetween.

5 The first holder 210 is attached to a first end 224 of a carrier rod 226 at the distal ends 206 of the members 202. The second holder 212 is slidably received on the carrier rod 226. In the condition shown in FIG. 11, the members 202 are arranged about the carrier rod 226 in a substantially equally spaced manner and generally aligned with the longitudinal axis A of the carrier rod 226. The occluding body 214 extends in a generally
10 radial manner from the carrier rod 226 at a mid-point between the proximal 204 and distal ends 206 of the inextensible members. In the arrangement shown in FIG. 11, the implant 200 forms an elongated apparatus or article that generally extends along longitudinal axis A. The elongate form of the implant 200 permits it to be tightly compressed and inserted through an intravenous delivery mechanism and in the form shown is referred to as being in the insertion condition.
15

In operation, a driving implement 228, (e.g., a plastic tube) can be placed over the carrier rod 226 in contact with the second holder 212. The driving implement 228 is slid along or moved toward the first substantially fixed holder 210 (i.e., toward the first end
20 224 of the carrier rod 226) along the carrier rod 226. Generally, as will be further described, when the driving implement 228 is moved toward the first holder 210 the two holders 210, 212 are driven relatively closer together, and the implant 220 is changed into a deployed condition.

25 FIGS. 5 - 8 show the implant 200 in a perspective view in various conditions of deployment. As can be seen in these figures, moving the two holders 210, 212 together at first tends to cause the inextensible members 202 at the distal end to assume a gently outwardly bowed configuration with respect to the longitudinal axis A of the carrier rod 226. This outwardly bowed configuration pulls the expansible occluding body 214 into
30 a tensioned radial disk shape.

Further moving the driving implement 228 towards the first holder 210 along the carrier rod 226 causes a first portion 230 of the inextensible members 202 located between the

first holder 210 and the occluding body 214, to assume a more bowed, almost semi-circular shape where the distal ends 206 of the members 202 attach to the first holder 210 in a nearly perpendicular direction with respect to the longitudinal axis A of the carrier rod 226. A second portion 232 of the inextensible members 202 at the proximal
5 end tends to remain relatively parallel to the longitudinal axis A at first.

The inextensible members 202 are shown in FIG. 7 in a condition in response to yielding to further compression. As shown, the first portions 230 of the members 202 have started to twist or spiral about the carrier rod 226 forming a plurality of generally radial
10 loops (with respect to the axis of the carrier rod). What then happens is that the first portion 230 then passes through a critical point, whereupon each wire in this portion 230 snaps into a generally radially-extending loop, yielding a somewhat concave petal-shaped structure at the distal side of the occluding body 214. Further compressing the second portion 232 likewise results in the formation of similar loops in a petal-shaped
15 structure on the proximal side of the occluding body 214.

FIGS. 8 and 9 show the implant 200 in a perspective view in a fully deployed condition. Both the first portion 230 and second portion 232 have responded to the compressing motion by twisting away from the axial direction A. Thereby, the first portion 230 of the
20 members have resolved into a first fixation structure 230' adjacent the distal face 216 of the occluding body. Similarly, the second portion 232 of the members 202 have resolved into a second fixation structure 232' adjacent the proximal face 218 of the occluding body 214. The overlapping spiral shape of both the first and second fixation structure 230', 232' is a stable shape, that locks the implant 200 into a stable occluding
25 or deployed condition upon the locking holders 210, 212 being driven together by the driving implement 228, as shown in FIG. 11.

FIG. 10 shows a perspective view of a portion of the implant without the occluding body and members or carrier rod. Thus, the first and second holders or hubs 210, 212
30 may be seen in more detail. The first and second holders 210, 212 may be adapted to be placed onto the carrier rod (not shown) by hollow central shafts 234, 236. Located about the central shafts 234, 236 are annular portions 238, 240 with a plurality of slots 242 or attachment points sized to fixedly receive the ends of the members 202. The slots 242

may extend to the periphery 244 of the annular portions 238, 240 to allow the members 202 to move from a longitudinal orientation to a radial orientation.

5 An extending tooth 246 may be formed on one of the first and second holders 210, 212 or in the alternate, the carrier rod (not shown) to engage and form a locking element with a corresponding recess (not shown) formed in one or both of the first and second holders 210, 212. In this manner, the implant 200 becomes locked into a fully deployed or final occluding condition upon being driven together by the driving implement by engagement of the tooth 246 and the recess.

10

The invention has been carefully described in the above-mentioned examples, and therefore the idea should be clearly understood that the invention is neither limited to the above described and on the drawings shown embodiment, but may be varied within the scope of the claims without departing from the concept of the invention. For example,
15 the invention can also be applied to other occluders, for example occluders as disclosed in US 6'623'508, US 6'077'291, US 6'599'308, US 6'506'204, US 6'379'368 and US 2003/0144694.

CLAIMS

1. An implant for occluding a passage in a circulatory system, the implant being compressible for insertion through a delivery mechanism and being deployable or
5 expansible for occluding the passage in the circulatory system, wherein the implant is at least partially made of at least some biodegradable material.
2. The implant of claim 1, the implant comprising thin elongate members being generally aligned with each other when the implant is in a compressed state and being
10 outwardly bowed in a deployed or expanded state, wherein the members are at least partially made of at least some biodegradable material.
3. The implant of claim 1, the implant comprising an occluding body, the occluding body being compressed, preferably folded, in a compressed state and expanded in
15 a deployed or expanded state, wherein the occluding body is at least partially made of at least some biodegradable material.
4. The implant of claim 1, the implant comprising thin elongate members being generally aligned with each other in a compressed state and being outwardly bowed
20 in a deployed state and the implant further comprising an occluding body, the occluding body being compressed, preferably folded, in the compressed state and expanded in the deployed or expanded state, wherein this occluding body is attached to the elongate members and wherein at least one of said elongate members and said occluding body is at least partially made of at least some biodegradable
25 material.
5. The implant of one of claims 3 or 4, wherein the occluding body is a generally disc-shaped member.
- 30 6. An implant for occluding a passage in a circulatory system, comprising:
a plurality of thin, preferably stiff, members each having a proximal and a distal end;
a first holder to which the distal ends of said members are attached;

a second holder to which the proximal ends of said members are attached;
an expansible, preferably foldable, occluding body attached to said members;
said plurality of members with said occluding body forming an elongated article
extending along a longitudinal axis and being adapted for insertion through a de-
livery mechanism in an insertion condition;

said members being attached to said first and second holders and the distance be-
tween said holders being reduceable in a manner to cause said members to execute
a twisting motion relative to said axis to yield a plurality of generally radially ex-
tending loops forming at least one fixation structure, thereby expanding, prefera-
bly unfolding, the occluding body and

said at least one fixation structure being fixable in a final occluding condition,
characterized in that one or more of said plurality of stiff members, said first
holder, said second holder and said expansible occluding body is made of at least
some biodegradable material.

7. The implant of claim 6 further comprising a carrier rod releasably attached to said
first holder and upon which said second holder is slidably received and
a driving implement on said carrier rod, said driving implement contacting said
second holder and movable toward said first holder along said carrier rod.

8. The implant according to one of claims 6 or 7, wherein said occluding body is
arranged at a point intermediate said first and second holders, said occluding body
having a distal and proximal face.

9. The implant according to one of claims 6 to 8, wherein said radially extending
loops form a first fixation structure adjacent said distal face of said occluding
body and a second fixation structure adjacent said proximal face of said occluding
body.

10. The implant of according to one of claims 2 to 9, wherein said plurality of mem-
bers are formed completely of said biodegradable material.

11. The implant according to one of claims 6 to 10, wherein said plurality of members

and said expansive occluding body are formed completely of said biodegradable material.

- 5 12. The implant according to one of claims 1 to 11, wherein said biodegradable material is one or more of PLLA, PDLA, PGA, polydioxanone, polycaprolactone, polygluconate, polylactic acidpolyethylene oxide copolymers, polyhydroxybutYrate, polyanhydride, polyphosphoester and poly amino acids.
- 10 13. The implant according to one of claims 6 to 12, further comprising a locking element fixing said first and second fixation structures in a final occluding condition upon being driven together by said driving implement.
- 15 14. The implant according to claim 13, wherein said locking element comprises an extending tooth located on one of said first and second holders which engages with a corresponding recess formed in the ether of said first and second holders upon being driven together by said driving implement.
- 20 15. The implant according to one of claims 6 to 14, wherein said members are attached to said first holder at a first angle of inclination relative to said axis and said members are attached to said second holder at a second angle of inclination which is different from said first angle.
- 25 16. The implant according to one of claims 6 to 15, wherein said twisting motion causes said members attached to said first holder to initially bulge radially outwardly and then snap into an inverted condition having a concave shape for said radially extending loops of said first fixation structure, with the concavity facing said first holder.
- 30 17. The implant according to one of claims 6 to 16, wherein said members are generally inextensible and have a thickened portion where said members attach to said expansible occluding body.
18. The implant according to one of claims 6 to 17, wherein each said first and second

holders include a hollow central shaft portion and an annular hub portion positioned about the central shaft portion.

- 5 19. The implant of claim 18, wherein each said annular hub portion includes a plurality of slots adapted to respectively receive one of said proximal and distal ends of said members.
- 10 20. The implant of claim 19, wherein each of said slots extend to an outer periphery of said annular hub portions of said first and second holders to permit said inextensible members to pivot from a first orientation generally parallel to said longitudinal axis to a second orientation generally radial with respect to said longitudinal axis.

Fig. 1

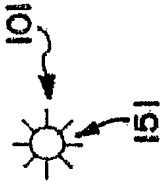
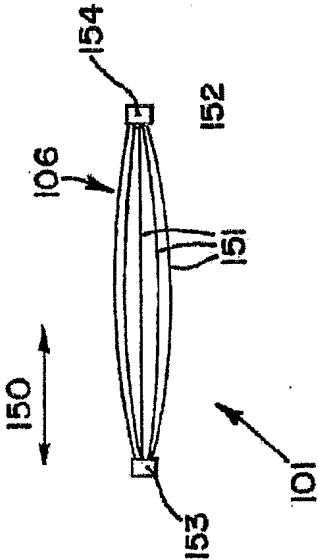


Fig. 2

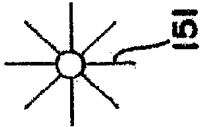
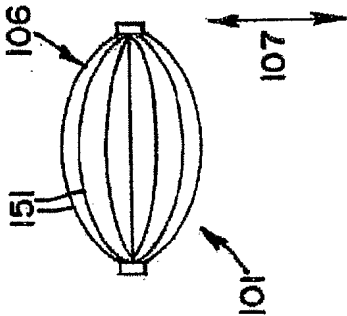
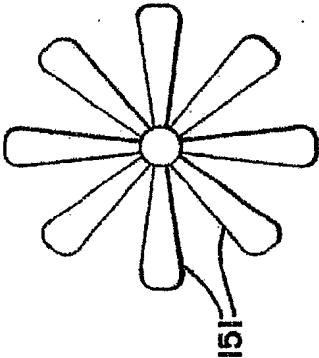
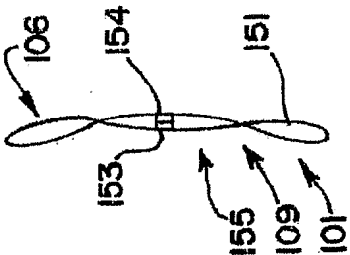


Fig. 3



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Fig. 2A

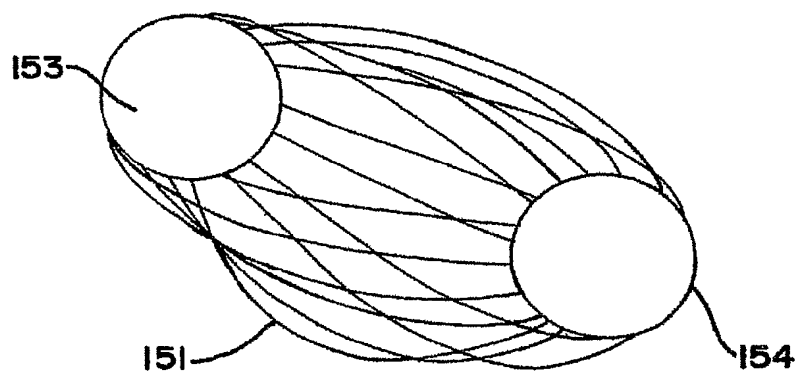


Fig. 3A

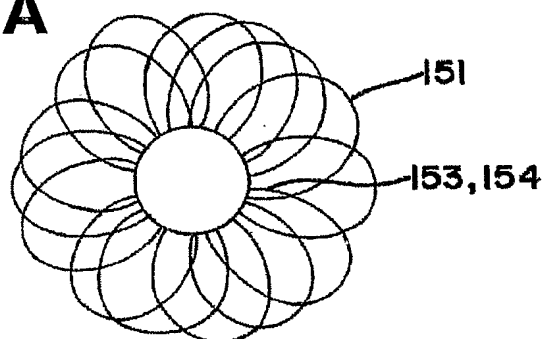


Fig. 4

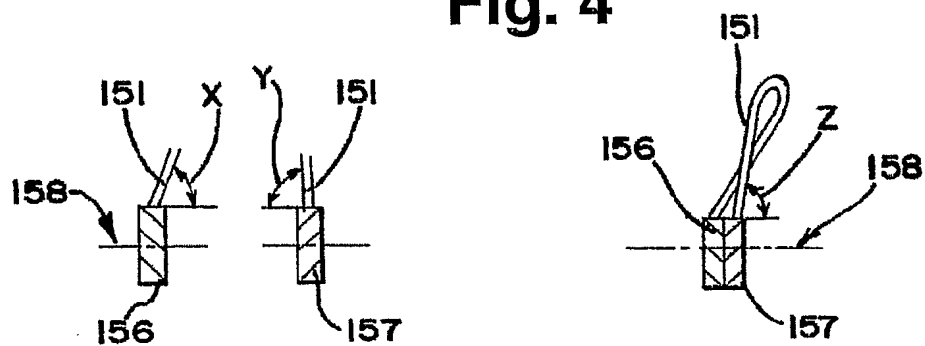


Fig. 5

Fig. 6

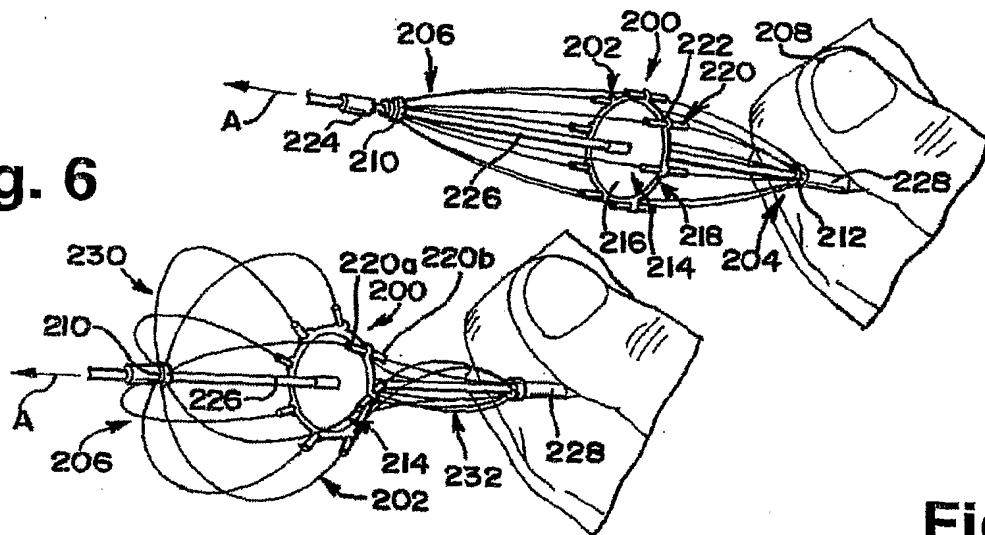


Fig. 8

Fig. 7

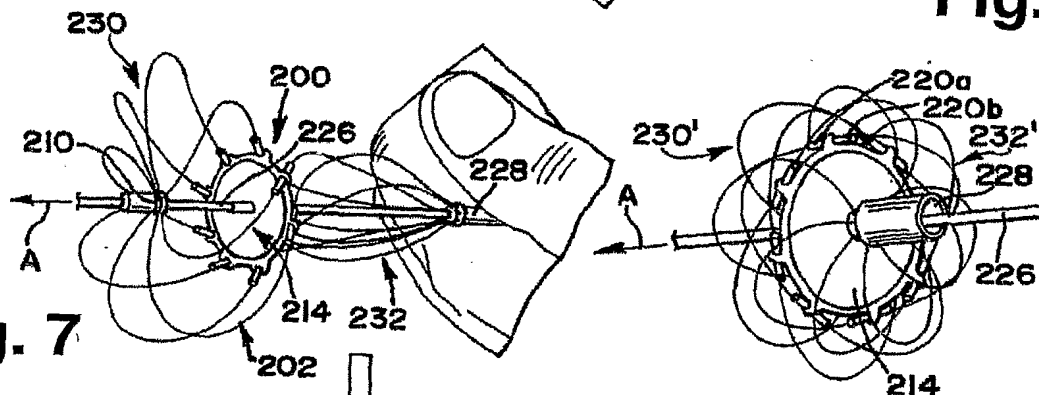
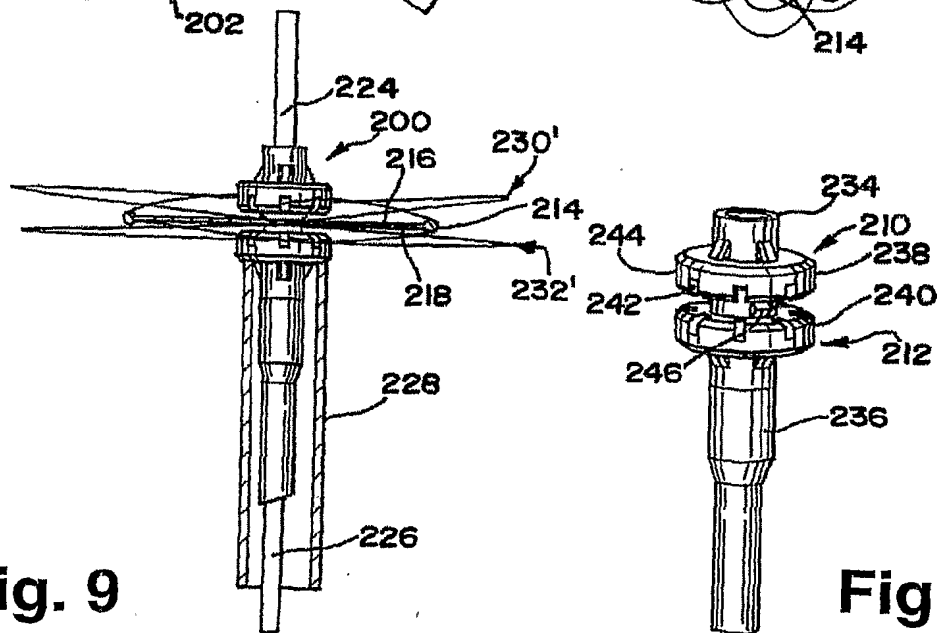


Fig. 9

Fig. 10



INTERNATIONAL SEARCH REPORT

International Application No

PC1/CH 03/00776

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B17/00 A61B17/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 432 134 B1 (ANSON ET AL.) 13 August 2002 (2002-08-13) abstract; figures column 2, line 64 - column 3, line 2 column 3, lines 50-55	1, 3, 5, 10, 12
Y		2, 4, 6-9, 11, 13-20
Y	WO 02/38051 A (CARAG AG) 16 May 2002 (2002-05-16) cited in the application the whole document	2, 4, 6-9, 11, 13-20
X	US 6 355 052 B1 (NEUSS ET AL.) 12 March 2002 (2002-03-12) abstract; figures column 9, lines 40-54	1-5, 12
	-/--	



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Patent family members are listed in annex.

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Date of the actual completion of the international search

2 March 2004

Date of mailing of the international search report

08/03/2004

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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X	EP 0 927 540 A (YOKOGAWA MEDICAL SYSTEMS, LTD.) 7 July 1999 (1999-07-07) paragraphs '0008!, '0021!; claims 6,7 -----	1,3,12

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